

the limitations on exemptions in subpart E of part 20 of this chapter.

[39 FR 44657, Dec. 24, 1974, as amended at 42 FR 15676, Mar. 22, 1977; 46 FR 38074, July 24, 1981]

**§ 730.8 Misbranding by reference to filing; filing does not constitute an admission.**

(a) The filing of an experience report does not in any way constitute approval of the firm or the cosmetic product by the Food and Drug Administration. Any representation in labeling or advertising that creates an impression of official approval because of such filing will be considered misleading.

(b) The filing of an experience report does not in any way constitute an admission by the person filing the report that the alleged experience was the result of an ingredient or ingredients in the cosmetic product, or of any other fact.

**PART 740—COSMETIC PRODUCT WARNING STATEMENTS**

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AUTHORITY: Secs. 201, 301, 502, 505, 601, 602, 701, 704 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 331, 352, 355, 361, 362, 371, 374).

**Subpart A—General**

**§ 740.1 Establishment of warning statements.**

(a) The label of a cosmetic product shall bear a warning statement whenever necessary or appropriate to prevent a health hazard that may be associated with the product.

(b) The Commissioner of Food and Drugs, either on his own initiative or on behalf of any interested person who has submitted a petition, may publish a proposal to establish or amend, under subpart B of this part, a regulation prescribing a warning for a cosmetic. Any such petition shall include an adequate factual basis to support the petition, shall be in the form set forth in part 10 of this chapter, and will be published for comment if it contains reasonable grounds for the proposed regulation.

[40 FR 8917, Mar. 3, 1975, as amended at 42 FR 15676, Mar. 22, 1977]

**§ 740.2 Conspicuousness of warning statements.**

(a) A warning statement shall appear on the label prominently and conspicuously as compared to other words, statements, designs, or devices and in bold type on contrasting background to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use, but in no case may the letters and/or numbers be less than  $\frac{1}{16}$  inch in height, unless an exemption pursuant to paragraph (b) of this section is established.

(b) If the label of any cosmetic package is too small to accommodate the information as required by this section, the Commissioner may establish by regulation an acceptable alternative method, e.g., type size smaller than  $\frac{1}{16}$  inch in height. A petition requesting such a regulation, as an amendment to this section, shall be submitted to the Dockets Management Branch in the form established in part 10 of this chapter.

[40 FR 8917, Mar. 3, 1975, as amended at 42 FR 15676, Mar. 22, 1977]

**Subpart B—Warning Statements**

**§ 740.10 Labeling of cosmetic products for which adequate substantiation of safety has not been obtained.**

(a) Each ingredient used in a cosmetic product and each finished cosmetic product shall be adequately substantiated for safety prior to marketing. Any such ingredient or product whose safety is not adequately substantiated prior to marketing is

misbranded unless it contains the following conspicuous statement on the principal display panel:

*Warning*—The safety of this product has not been determined.

(b) An ingredient or product having a history of use in or as a cosmetic may at any time have its safety brought into question by new information that in itself is not conclusive. The warning required by paragraph (a) of this section is not required for such an ingredient or product if:

(1) The safety of the ingredient or product had been adequately substantiated prior to development of the new information;

(2) The new information does not demonstrate a hazard to human health; and

(3) Adequate studies are being conducted to determine expeditiously the safety of the ingredient or product.

(c) Paragraph (b) of this section does not constitute an exemption to the adulteration provisions of the Act or to any other requirement in the Act or this chapter.

[40 FR 8917, Mar. 3, 1975]

**§ 740.11 Cosmetics in self-pressurized containers.**

(a)(1) The label of a cosmetic packaged in a self-pressurized container and intended to be expelled from the package under pressure shall bear the following warning:

*Warning*—Avoid spraying in eyes. Contents under pressure. Do not puncture or incinerate. Do not store at temperature above 120° F. Keep out of reach of children.

(2) In the case of products intended for use by children, the phrase “except under adult supervision” may be added at the end of the last sentence in the warning required by paragraph (a)(1) of this section.

(3) In the case of products packaged in glass containers, the word “break” may be substituted for the word “puncture” in the warning required by paragraph (a)(1) of this section.

(4) The words “Avoid spraying in eyes” may be deleted from the warning required by paragraph (a)(1) of this section in the case of a product not expelled as a spray.

(b)(1) In addition to the warning required by paragraph (a)(1) of this section, the label of a cosmetic packaged in a self-pressurized container in which the propellant consists in whole or in part of a halocarbon or a hydrocarbon shall bear the following warning:

*Warning*—Use only as directed. Intentional misuse by deliberately concentrating and inhaling the contents can be harmful or fatal.

(2) The warning required by paragraph (b)(1) of this section is not required for the following products:

(i) Products expelled in the form of a foam or cream, which contain less than 10 percent propellant in the container.

(ii) Products in a container with a physical barrier that prevents escape of the propellant at the time of use.

(iii) Products of a net quantity of contents of less than 2 ozs. that are designed to release a measured amount of product with each valve actuation.

(iv) Products of a net quantity of contents of less than ½ oz.

(c)(1) In addition to the warnings required by paragraphs (a)(1) and (b)(1) of this section, the label on each package of a cosmetic in a self-pressurized container in which the propellant consists in whole or in part of a fully halogenated chlorofluoroalkane (chlorofluorocarbon) shall bear the following warning:

*Warning*—Contains a chlorofluorocarbon that may harm the public health and environment by reducing ozone in the upper atmosphere.

(2) The warning required by paragraph (c)(1) of this section shall appear on an appropriate panel with such prominence and conspicuousness as to render it likely to be read and understood by ordinary individuals under normal conditions of purchase. The warning may appear on a firmly affixed tag, tape, card, or sticker or similar overlabeling attached to the package. The warning shall comply in all other respects with § 740.2, e.g., type-size requirements.

(3) The warning required by paragraph (c)(1) of this section is applicable only to self-pressurized containers that use a chlorofluorocarbon in whole or in part as a propellant to expel from the

container liquid or solid material different from the propellant.

[40 FR 8917, Mar. 3, 1975, as amended at 42 FR 22033, Apr. 29, 1977; 54 FR 39640, Sept. 27, 1989]

**§ 740.12 Feminine deodorant sprays.**

(a) For the purpose of this section, the term “feminine deodorant spray” means any spray deodorant product whose labeling represents or suggests that the product is for use in the female genital area or for use all over the body.

(b) The label of a feminine deodorant spray shall bear the following statement:

*Caution*—For external use only. Spray at least 8 inches from skin. Do not apply to broken, irritated, or itching skin. Persistent, unusual odor or discharge may indicate conditions for which a physician should be consulted. Discontinue use immediately if rash, irritation, or discomfort develops.

The sentence “Spray at least 8 inches from skin” need not be included in the cautionary statement for products whose expelled contents do not contain a liquified gas propellant such as a halocarbon or hydrocarbon propellant.

(c) Use of the word “hygiene” or “hygienic” or a similar word or words renders any such product misbranded under section 602(a) of the Federal Food, Drug, and Cosmetic Act. The use of any word or words which represent or suggest that such products have a medical usefulness renders such products misbranded under section 502(a) of the Act and illegal new drugs marketed in violation of section 505 of the Act.

[40 FR 8929, Mar. 3, 1975]

**§ 740.17 Foaming detergent bath products.**

(a) For the purpose of this section, a foaming detergent bath product is any product intended to be added to a bath for the purpose of producing foam that

contains a surface-active agent serving as a detergent or foaming ingredient.

(b) The label of foaming detergent bath products within the meaning of paragraph (a) of this section, except for those products that are labeled as intended for use exclusively by adults, shall bear adequate directions for safe use and the following caution:

*Caution*—Use only as directed. Excessive use or prolonged exposure may cause irritation to skin and urinary tract. Discontinue use if rash, redness, or itching occurs. Consult your physician if irritation persists. Keep out of reach of children.

(c) In the case of products intended for use by children, the phrase “except under adult supervision” may be added at the end of the last sentence in the caution required by paragraph (b) of this section.

[51 FR 20475, June 5, 1986]

**§ 740.18 Coal tar hair dyes posing a risk of cancer.**

(a) The principal display panel of the label and any labeling accompanying a coal tar hair dye containing any ingredient listed in paragraph (b) of this section shall bear, in accordance with the requirements of § 740.2, the following:

*Warning*—Contains an ingredient that can penetrate your skin and has been determined to cause cancer in laboratory animals.

(b) Hair dyes containing any of the following ingredients shall comply with the requirements of this section: (1) 4-methoxy-*m*-phenylenediamine (2,4-diaminoanisole) and (2) 4-methoxy-*m*-phenylenediamine sulfate (2,4-diaminoanisole sulfate).

[44 FR 59522, Oct. 16, 1979]

EFFECTIVE DATE NOTE: At 47 FR 7829, Feb. 23, 1982, the effectiveness of § 740.18 was stayed until further notice. The stay was effective Sept. 18, 1980.

**PARTS 741—799 [RESERVED]**